White paper:
Archetype paradigm: an ICT revolution is needed

The *EPR of the future demands flexible plug-and-play
exchange between ICT systems.*

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Archetype paradigm: an ICT revolution is needed

1- Summary

The way in which Information and Communication Technology (ICT) supports healthcare processes is set to improve dramatically over the coming years. In the current - but soon to be obsolete – paradigm, data, information and knowledge are mostly embedded within software. A new paradigm will allow ICT systems to communicate in plug-and-play fashion without any additional software reprogramming. European R&D projects in Medical Informatics have been working on such a solution of this sort over the past 20 years. This has resulted in three European standards, including two that are on track to become accepted as ISO standards. These European standards can also be applied outside health care.

This paper discusses both present health care with the current, but old, ICT paradigm and future care, in which the new paradigm is to play a major part.

The current message paradigm increasingly will prove to be too inflexible and not scalable to national levels. In contrast the new European standards, based on the new Archetype paradigm, make ICT-systems and exchange between them flexible and thus very scalable. ICT-systems under the new standards can be federated. The control of over who has access stays with the healthcare provider and the patient.

The ICT industry will need to change if the new health care is to be facilitated adequately. ICT value chains will come into being. New ICT players will take over the market through creative destruction, unless the existing players are quick enough to adapt to the new demands in health care.

Through legislation and regulation based on the European standards governments may contribute to a high-quality ICT provision in their countries, in line with European economic (market) development. This greatly contributes to the realisation of the European ICT objectives for 2010[1]

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[1] I2010 is the European comprehensive strategy for the information society 2005-2010 in Europe.

http://ec.europa.eu/information_society/eeurope/i2010/index_en.htm

2- Current (care) processes and ICT support

Until now health care has been delivered in columns that have been called 'stove pipes' (figure 1). It implies that per care sector (general practice, hospital, home care, etc) everything is organized, managed and financed within that sector itself. So is automation. Within a single sector much care is organised in a unique geographical or clinical context (such as dermatology, pharmacy). This ghetto-like automation greatly impedes collaboration between care providers. And as soon as care-providers do start to collaborate they are faced with resistance stemming from bureaucratic rules or localised funding mechanisms. Even when all these hurdles have been overcome, ICT itself eventually proves to be a barrier because the software in ICT information-systems has been vertically developed and organized in a 'stove pipe'. The ICT provision is usually regarded, used and built as a single monolithic island application.

- *Healthcare is presently organised in stove pipes .*
- *This results in ICT applications serving vertical markets.*
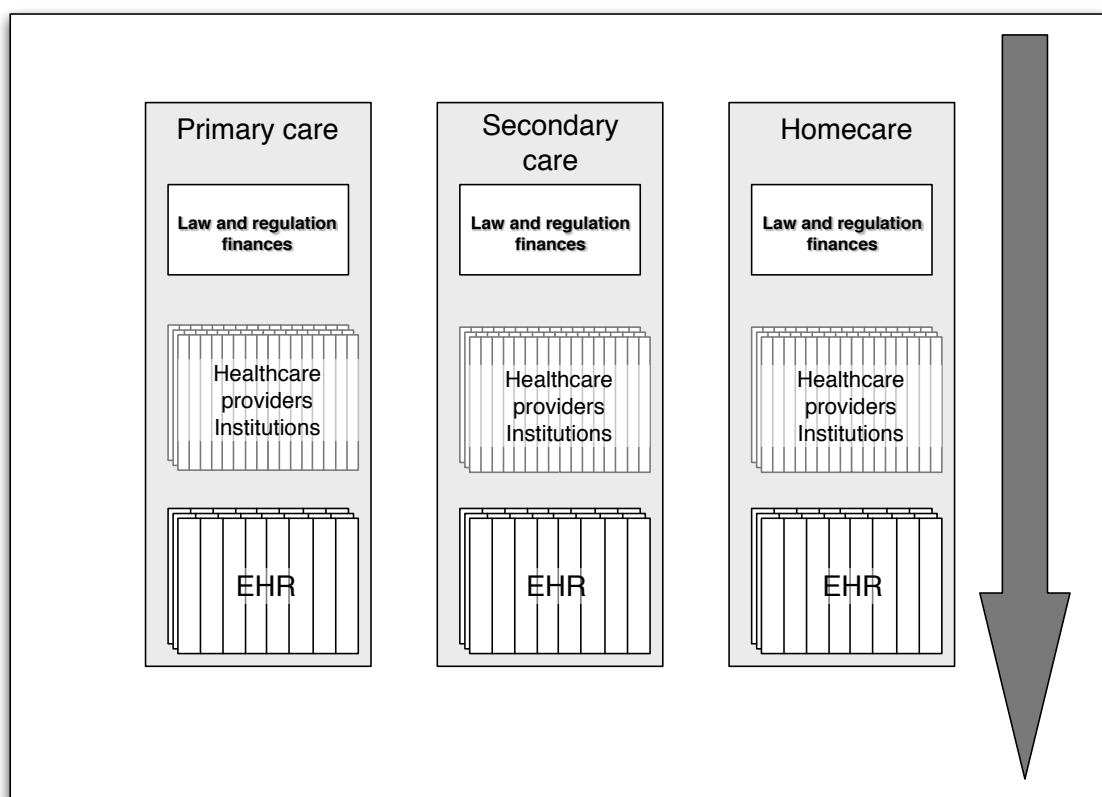- *It leads to island automation in isolated ghettos.*

Figure 1. Present organisation of health care and ICT stove pipes

3- The old ICT paradigm: the messages paradigm

ICT systems are based on the old paradigm[2] are characteristically implemented in one specific sector only. Communication among them takes place through the old Messages paradigm -trail-blazed by HL7-, in whose terms the ICT islands communicate with each other.

Each ICT system currently on the market has its own information and database model. A large amount of domain specific

- *The message paradigm results in solutions that do not scale*
- *And do not provide the needed plug-and-play semantic interoperability*

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[2] A world view underlying the theories and methodology of a particular scientific subject.

knowledge is hard-wired into the software in a way that barely leaves room for flexibility. As medical views change, or as new data need to be recorded and exchanged, an adaptation of the software is called for. For instance, in the general practice sector in the Netherlands there are several General Practice Information Systems (GPIS) each with their own information and database model. Communication between GPISs (General Practice Information Systems) takes places through a standardised information model with which Edifact messages are composed for the exchange of data.

As new forms of cooperation arise it will become necessary for general practitioners to collaborate with specialists and with home care workers and therefore all GPIS applications will need to implement the same messages in a uniform manner (figure 2).
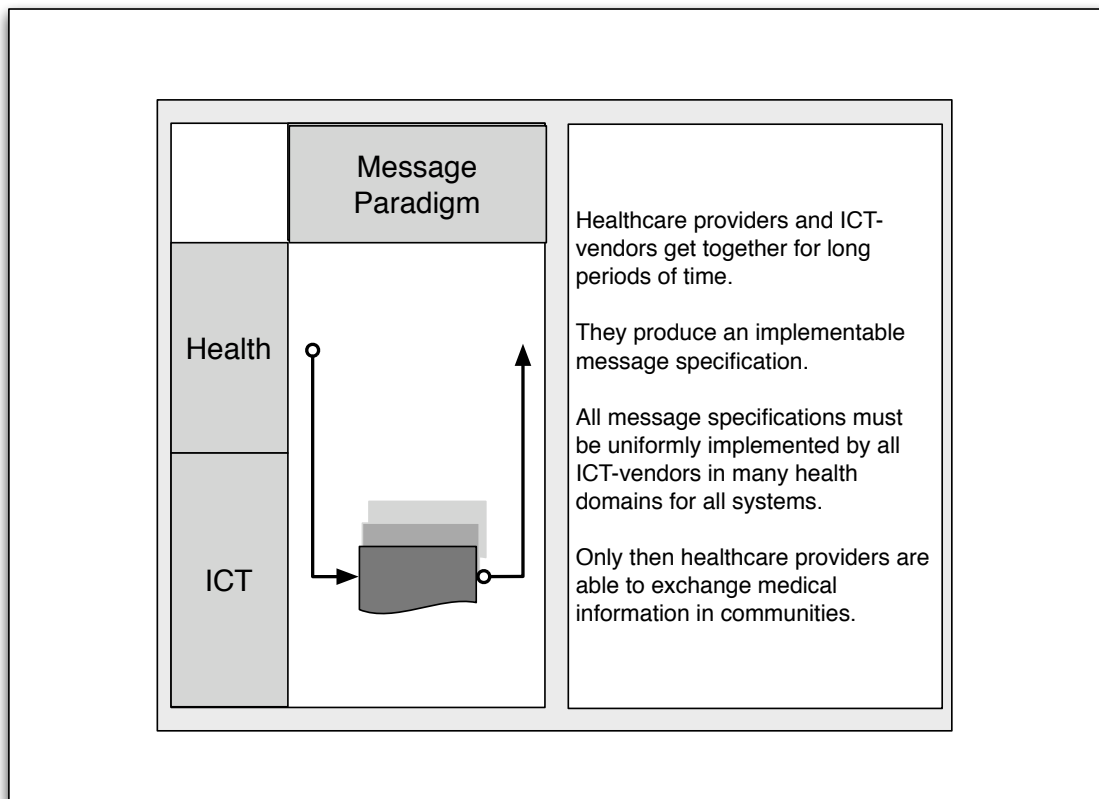

Figure 2. The Messages Paradigm

Each new collaboration thus demands exchange of data between information systems. This requires several messages and the composition of ever more new messages. Even the set-up of one single message specification puts a heavy demand on resources (time and money). The uniform implementation of such a new message in all systems and on all locations calls for a heavy investment of time and money. Each new set of demands resulting from new or altered forms of collaboration has to go through the full, rigid standardisation process. In each care domain much is susceptible to change. It follows that changes allowed by the Messages paradigm come at a high price. This approach is neither flexible nor scalable enough to be implemented in a national health care system, where collaborating care professionals whose work is becoming more and more integrated, but who at the same time need to respond in flexible ways to ever new challenges, need to exchange data, information and knowledge of an ever-evolving variety of different forms.

- *HL7 v2 and HL7 v3 are based on the Message Paradigm.*
- *All conformant ICT-systems have to map the internal information and database model onto the model designed for a particular message specification.*
- *Although derived from the same HL7v3 RIM all specifications are unique.*

The Messages paradigm, such as with HL7 v3[3], uses a Reference Information Model (RIM) to create a number of Refined Message Information Models (R-MIMs), Hierarchical Message Description (HMDs) via a Domain Message Information Model (D-MIM) (figure 3). These are subsequently translated into a set of implementable message specifications . Each message will have to be implemented in each ICT system because each system uses its proprietary information model that is used in the persistence layer in a database. Each set of messages is created and established in a large community that may comprise the whole world, but at least one country.
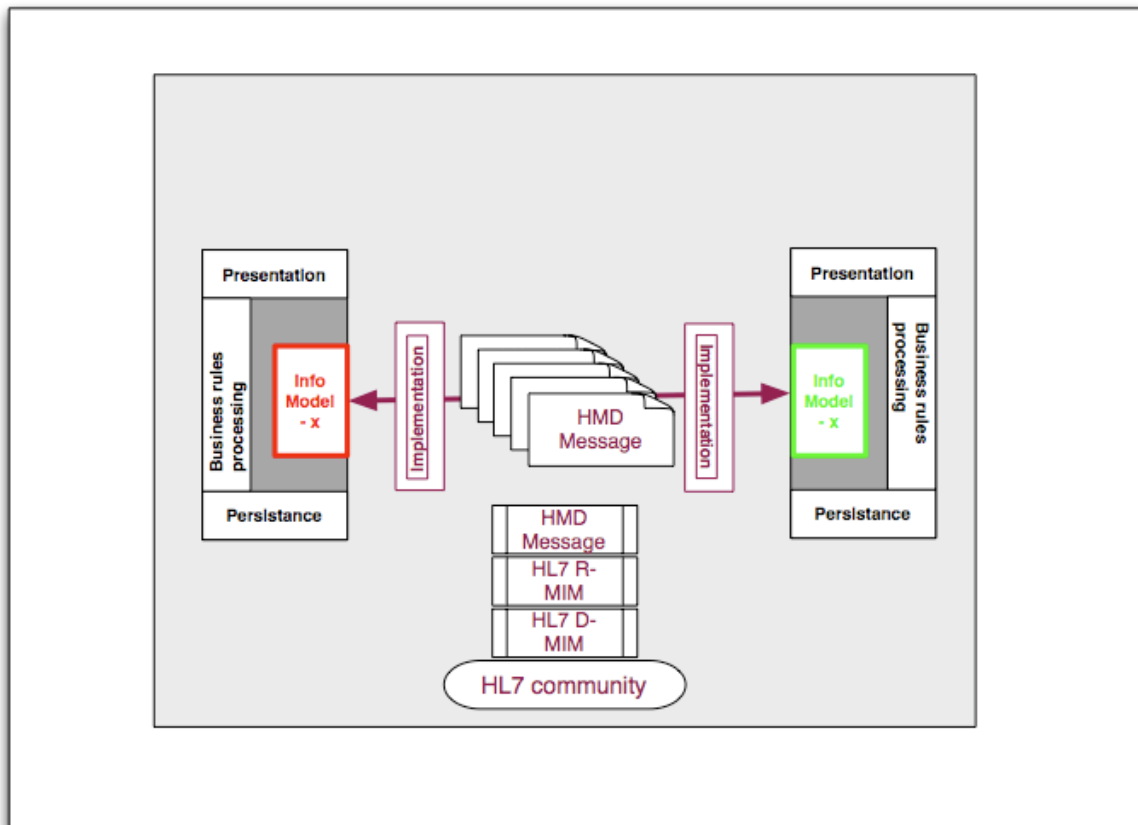

Figure 3. The HL7 process of composing messages

International experience so far has indicated that the Message paradigm can hardly be called successful. Commercial EDI message traffic[4] based on Edifact has notably failed to take off in spite of the large amount of attention from large companies and organisations (such as UN/Cefact and OASIS[5]). Many e-government projects hardly yield any noticeable success even after many years and many hundred of millions of Euros spent. When message standards based on CEN[6] (Europe) and HL7v2[7] (USA) are implemented in an useful fashion, then this is mainly within a single health care organisation and at considerable expenses. Large enterprises in the image processing industry such as Philips, Agfa, Siemens, and GE have joined in IHE[8] (Integrating the Healthcare Enterprise) with the aim of improving and speeding up the message implementation process. Its initial aim was to exchange images, but also in IHE the implementation costs have remained high.

> - *Experiences show that the Message Pardigm is difficult to scale at National levels.*
> - *The Message Paradigm needs an resource intensive process like IHE to achieve some results.*
> - *The HL7v3 methodology is seriously questioned.*

HL7 has successfully promoted its version 3. In England (Connecting for Health[9]) and the Netherlands (NICTIZ[10]) a national health care infrastructure has been started up on the basis of the HL7v3 Reference Information Model (HL7v3 RIM) and the HL7-specific method for creating messages. In England there is a growing realisation that on the one hand HL7 message specifications are too rigid to be implemented in a flexible form and that on the other hand uniform implementation is too laborious and costly. There are also is a growing concern that the planned UK ICT infrastructure would not be able to cope with the enormous volume of the HL7v3 XML messages and would eventually get clogged[11]. Thus the use of HL7v3 XML messages as an exchange format is problematic[12]. In the academic world there is a growing number of substantive objections to HL7 RIM and to the methods used[13] in its development and marketing. A virtually lethal observation is that within HL7 there is no consensus about utterly basic definitions that are used in the RIM[14]. There are clear signs that in

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[4] http://en.wikipedia.org/wiki/UN_CEFACT

[5] http://ww/oasis-open.org

[6] http://www.cenorm.be

[7] http://www.HL7.org

[8] http:///www.IHE.org

[9] http://www.connectingforhealth.nhs.uk

[10] National Institute for ICT in Health
 http://www.NICTIZ.nl

[11] Personal communications by persons working for the NHS and British Telecom

[12] Paul Biron: http://www.w3.org/2005/05/25-schema/HL7.html

[13] Barry Smith and others
http://ontology.buffalo.edu/medo/HL7_2004.pdf
http://hl7-watch.blogspot.com

[14] An intense discussion Mid 2006 on the HL7 MNM-list with subject "Why is the document an act"

http://lists.hl7.org/read/messages?id=92595

England the NHS is looking for an alternative[15][16]. Australia has recently announced that it will not use HL7v3 for its national health care infrastructure[17].

4- The new paradigm: the Archetype/Template paradigm

In European medical informatics over the past fifteen years a large number of experts in R&D projects[18] have been occupied with the electronic patient record and the exchange between record systems. This has resulted in a number of mutually harmonised complementary European standards, which are on track to become ISO standards[19].

Since 2001 a group of European experts in the European Committee for Standardization (CEN) has been working on an exchange standard for the Electronic Patient Record that uses a new paradigm. This paradigm allows plug-and-play semantic interoperability between systems.

This approach implies that ICT suppliers implement one specification only once (figure 4). This specification is based on a generic model of each possible document. Totally independent

- *CEN/TC251 produced a new European standard for the EHR.*
- *It is based on a new paradigm:*
  The Archetype Paradigm.
- *It makes*
   Plug-and-Play semantic interoperability possible.

from the ICT supplier health care professionals collaborating in groups can subsequently record what they want to record and or exchange by means of the Archetype and Template Editor. The systems adapt these so called Archetypes and Templates without any intervention from the ICT supplier and without any re-programming. That is why the new paradigm may be called revolutionary.

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[15] e-mail en document by Laura Sato (NHS) sent to mnm@lists.hl7.org dd 7-9-2006

"The NHS National Programme for IT experience to date has identified a number of business issues related to HL7 V3 usability, mostly concerned with learnability, efficiency and satisfaction."

[16] Report dd 20-12-2006, Laura Sato. "Investigating implementing CEN 13606 with HL7 V3 and SNOMED CT – Final Report".
"Overall, ..., the use of 13606 / openEHR archetypes to establish clinical information requirements models and a common patient record architecture have the potential to save wide-spread project and application development costs in the longer term (by supporting the potential re- use of clinical semantic models, software, and patient record data)".

[17] Report dd 20-12-2006, Laura Sato. "Investigating implementing CEN 13606 with HL7 V3 and SNOMED CT – Final Report".
"Overall, ..., the use of 13606 / openEHR archetypes to establish clinical information requirements models and a common patient record architecture have the potential to save wide-spread project and application development costs in the longer term (by supporting the potential re- use of clinical semantic models, software, and patient record data)".

[18] GEHR, Synapses, Synapses in Use, HANSA, ...

[19] http://www.CENtc251.org
CEN/tc251 EN12504 ContSys (System of Concepts for Continuity of Care)
CEN/tc251 EN13606 EHRcom
CEN/tc251 EN12967 HISA (Health Information Services Architecture)

Further down in this document all three European standard will be presented in the chapter:
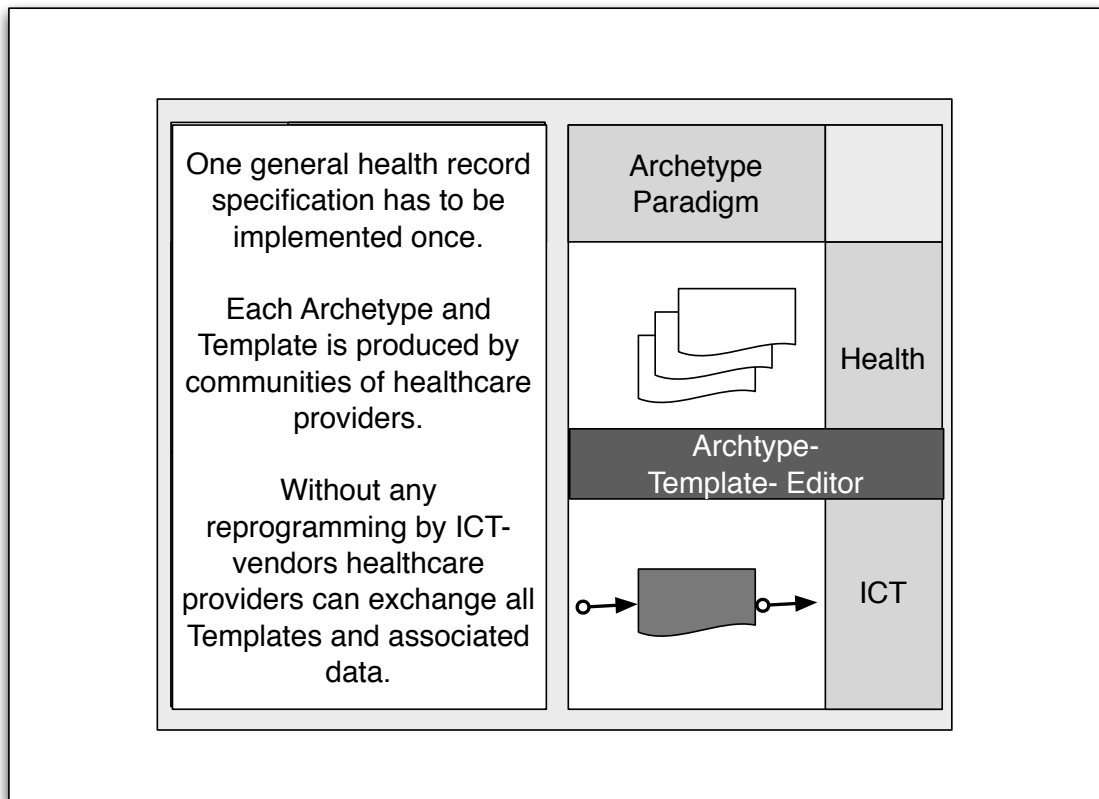"CEN/TC251 standards as the basis".

Figure 4. The new Archetype paradigm

The new Archetype paradigm operates with at least two models (figure 5). The first, the Reference Model, is a generic model for all possible kinds of records. In this model, the division, the signature, the versioning and the semantic linking of the parts of the record are defined. This Reference Model is implemented by the ICT supplier only once. The second model, the Archetype Reference Model, allows the specification of constraints to the first model exchangeably in Archetypes[20]. Archetypes contain what a community of care professionals wants to record and exchange on a clinical subject. For instance: laboratory results, the Apgar score, blood pressure measurements, weight measurement etc. The Archetype and Template Editor is based on this second model, i.e. the Archetype Reference Model. Archetypes are constraints on the Reference Model. All Archetype specifications, including the accompanying data to be exchanged, can subsequently, without re-programming of the ICT system, be read, recorded, retrieved, presented and exchanged.

- *Each cooperating community is able to define the templates it needs using archetypes.*
- *Each archetype and template can be read, stored, retrieved, presented and exchanged without any reprogramming.*
- *Archetypes and Templates are published via common repositories.*

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[20] http://en.wikipedia.org/wiki/Archetype_%28information_science
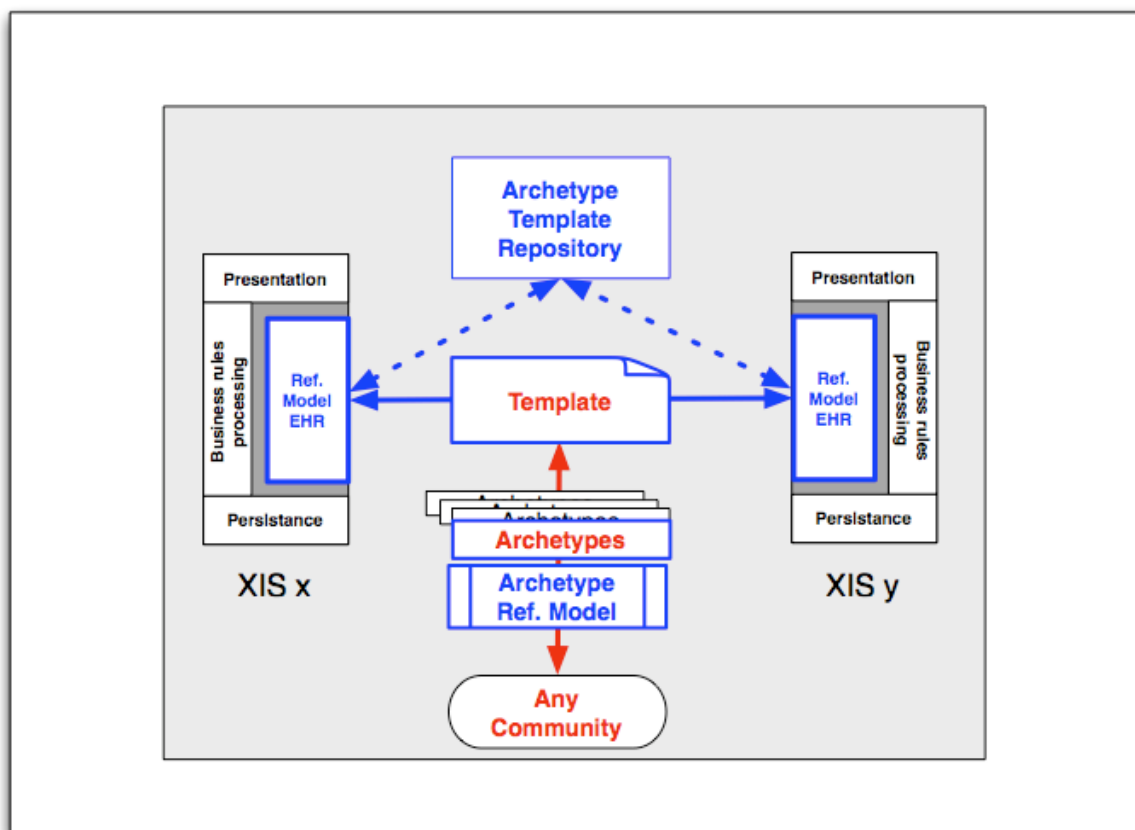
14-3-07

Figure 5. The EN13606 process for making Archetypes and Templates

Systems that are based on the new Archetype paradigm render any community, however small, capable of describing any Template it deems necessary for mutual cooperation, without the intervention of the ICT suppliers, simply by using the Archetype Editor (using part 2 of the European EHR communications standard EN13606). Each system makes use of an identical Reference Model for any Record (part 1 of the European EHRcom standard). All components can treat the information that is defined by Archetypes and Templates in an identical manner. All exchanged information can be recorded, read, presented ad exchanged without re-programming (implementing). Templates must be regarded as the information component of a cooperation contract between care providers.

A common service, the Archetype and Template Repository, where Archetypes and Templates can be stored and read, will be required to allow systems to interpret the information when they do not yet recognize the most recent Archetypes and Templates.

A complete separation between care domain and ICT domain offers many advantages. Data, information and knowledge can be defined and exchanged without the ICT supplier's intervention. ICT systems are able to offer care specific information in a more uniform manner. Storage, archiving and using old information remains always possible with the accompanying archetypes and templates. All information is presented to decision supporting systems in a uniform manner. Further advantages are scalability, flexibility and the ease with which providers themselves can adapt their systems to changing conditions. Because of the 'plug-and-play' nature ICT-systems can cooperate with other ICT-systems. The information about one patient stays stored at the source, the healthcare provider. Patient safety will increase, while the implementation costs will be reduced to a fraction of those demanded by the old Messages paradigm.

5- New style ICT support

If health care is to remain affordable and to continue meeting the changing demographic conditions, care professionals will be required to cooperate. To do so, they will need a mutual frame of reference.

A new style health care will necessitate a new style ICT provision. ICT support of collaborating care providers is too complex for a single application to solve the problem of storage and exchange. An ICT-information system , as well as any EPR system, will eventually consist of a number of integrated services.

Ministries of Health and the Ministries of Economic Affairs could start considering the creation of so-called Transition Arenas that would allow to experiment with fewer rules and new forms of collaboration in health care.

- *Healthcare will change so will the supporting ICT-systems.*
- *ICT-systems based on the new European EHR standard will facilitate collaborating healthcare providers.*

Collaboration between care providers implies the creation of 'communities'. The ICT systems must to the highest degree possible facilitate the fluidity of all care communities rather than prescribe what is to be stored and exchanged. Future EPRs must meet an EPR specification that supports them in a plug-and-play way.

Collaboration between care providers further implies that also the EPR systems and the functions, modules or services they contain collaborate with each other. For instance: the agenda functions could plug-and-play synchronize with each other if they were based on the same architecture standard.

- *ICT value chains will be formed.*
- *Several stacked ICT services will constitute one ICT application the healthcare provider will use.*
- *No longer one company will provide all needed services at all levels.*

Nowadays many ICT-information systems – certainly those in first-line care - are maintained by care providers themselves. This situation is considered less than optimal by the Dutch Ministry of Health, Welfare and Sport and by its Health Care Inspectorate. Unless a network of collaborating care providers can use optimally maintained and secured systems their trust in the system as a whole will be undermined. Much is to be gained if all information systems are hosted in controlled environments. When furthermore an Application Service Provider (ASP) offers additional services, such as support in meeting the Dutch NICTIZ demands for a Well Managed Care System, the optimization of information systems, archiving, extra services (such as the financial settlement of transactions) and communication, a Total Solution Hosting Provider (TSHP) will be constituted.

The supporting infrastructure supplied by the various telecom companies will provide every necessary form of communication.

An optimal ICT support for health care in the future will necessitate the creation of an ICT value chain (figure 6). This means that multiple collaborating ICT companies will market stacked services rather than a single application. An entity of services is the ICT-information system of the future. All these services do not need to be located on a single computer, or to operate via a single ASP supplier. Indeed, several of the latter may be involved. In each ICT layer of the ICT value chain companies should offer services making use of specific standards. On the basis of the standards, collaboration and market processes become possible in each ICT layer.
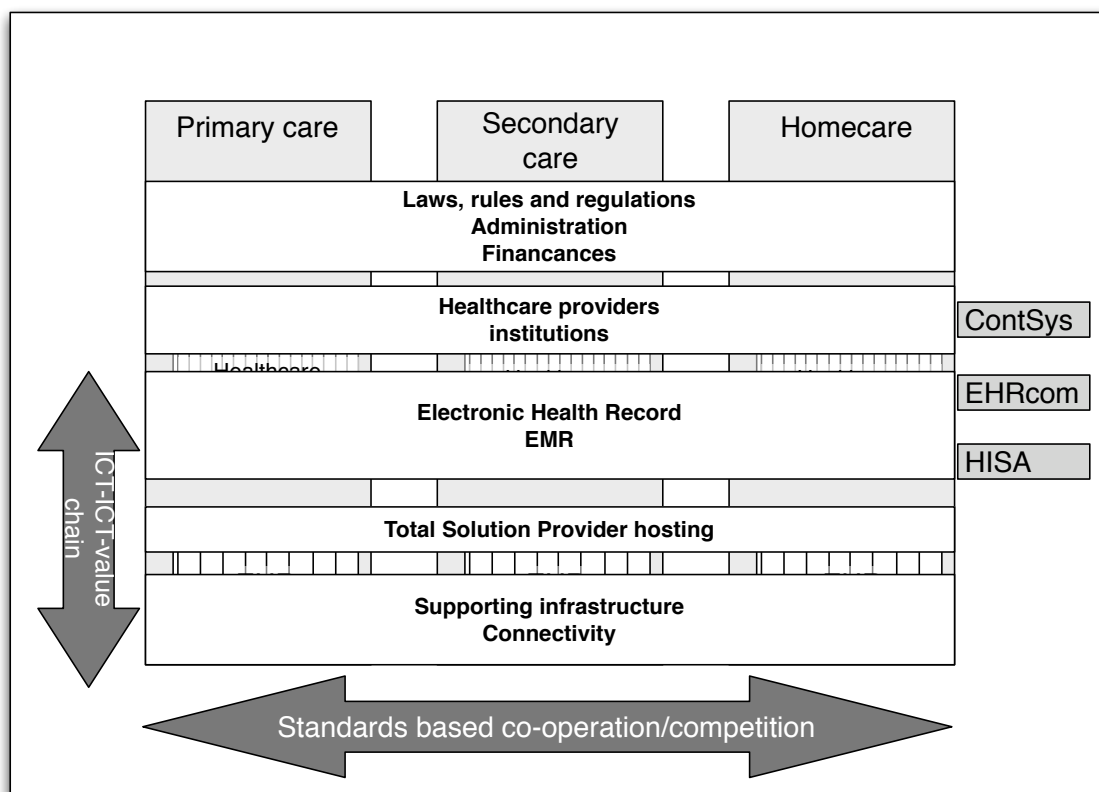
Figure 6. The new organization of health care and ICT

6- CEN/TC251 standards as a basis

CEN/TC251[21] has produced the following three standards that constitute a major contribution to plug-and-play semantic interoperability[22].

ContSys (EN12504 '*System of Concepts for Continuity of Care*) is a European standard that describes a system of concepts that empowers care providers to collaborate in the treatment of one or more patients.

The EHRcom standard (EN13606 '*Electronic Health Record Communication*) provides for the plug-and-play exchange of data, information and knowledge between EPR systems.

- *CEN/tc251 has published three exciting new European standards for eHealth.*
- *These European support the ambitious goals of Europe.*
- *The new Archetype Paradigm makes real plug-and-play possible,*

The CEN/ISO 13606 (EHRcom) standard defines the way in which clinical applications and electronic health record systems can communicate patient records. This standard helps to support shared patient care between healthcare organisations, and enables life-long care to be informed by a patient's full history whenever and wherever they next need health care. This is the first formal standard for electronic health record communication. Once it has been fully implemented and deployed across a regional or national healthcare network it will effectively create a virtual life-long health record for every patient. The standard is in five parts

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[21] www.centc251.org

[22] It can be observed that the Netherlands was one of the few countries opposing these new standards.

that specify how clinical information is to be represented, how privacy policies can be shared, and how requests for specific parts of an EHR can be made, and the resulting EHR extract be returned.

HISA (EN12967 '*Health Information Services Architecture*') is an architectural standard to describe unambiguously various services and application interfaces of parts of EPR systems (functions, modules, services). EPR systems that meet the HISA standard and the constituents can work together more easily.

7- The ultimate aim

The underlying philosophy of CEN/TC251 is to provide maximal support for ever-changing care providing processes with ICT systems, in a patient-safe way that also takes aspects of information security and privacy fully into account. For this purpose CEN/TC251 employs some ISO standards: 18308 '*Requirements for EHR-systems*' and ISO 22600 '*Privilege Management and Access Control*'.

- *CEN/tc251 European standards.*
- *The ultimate aim is to support plug-and-play semantic interoperability.*
- *Enabling an Information Economy and Knowledge Economy*

The CEN and ISO standards mentioned above contribute to the creation of an information economy [23] and a knowledge economy [24] (figure 7). People receive the data, interpret and synthesize them and convert them into knowledge and expertise. The information is documented in registrative systems. In several European member states care providers are obliged to document care, by, among others, a kind of Medical Treatment Agreement Act. When this documented information is received again by an individual it is in the form of data. This process is called the information economy. Documented information may also be converted into knowledge that in turn is applied when people process data into information. This is called the knowledge economy or hermeneutic cycle [25].

The European CEN/TC251 (and International ISO) standards make it possible for ICT systems to maximally support the information and knowledge economy. It is in addition to the world of messages.

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[23] Information economy is a loosely defined term to characterize an economy with increased role of informational activities and information industry.
http://en.wikipedia.org/wiki/Information_economy

[24] Knowledge Economy refers to the use of knowledge to produce economic benefits. The phrase came to prominence in New Zealand in the mid-to late-1990s as a way of referring to the manner in which various high-technology businesses, especially computer software, telecommunications and virtual services, as well as educational and research institutions, can contribute to a country's economy.
http://en.wikipedia.org/wiki/Knowledge_economy

[25] Hermeneutics may be described as the development and study of theories of the interpretation and understanding of texts. In contemporary usage, hermeneutics often refers to study of the interpretation of Biblical texts. However, it is more broadly used in contemporary philosophy to denote the study of theories and methods of the interpretation of all texts. The concept of "text" is here also extended beyond written documents to any number of objects subject to interpretation. A hermeneutic is defined as a specific system or method for interpretation, or a specific theory of interpretation.
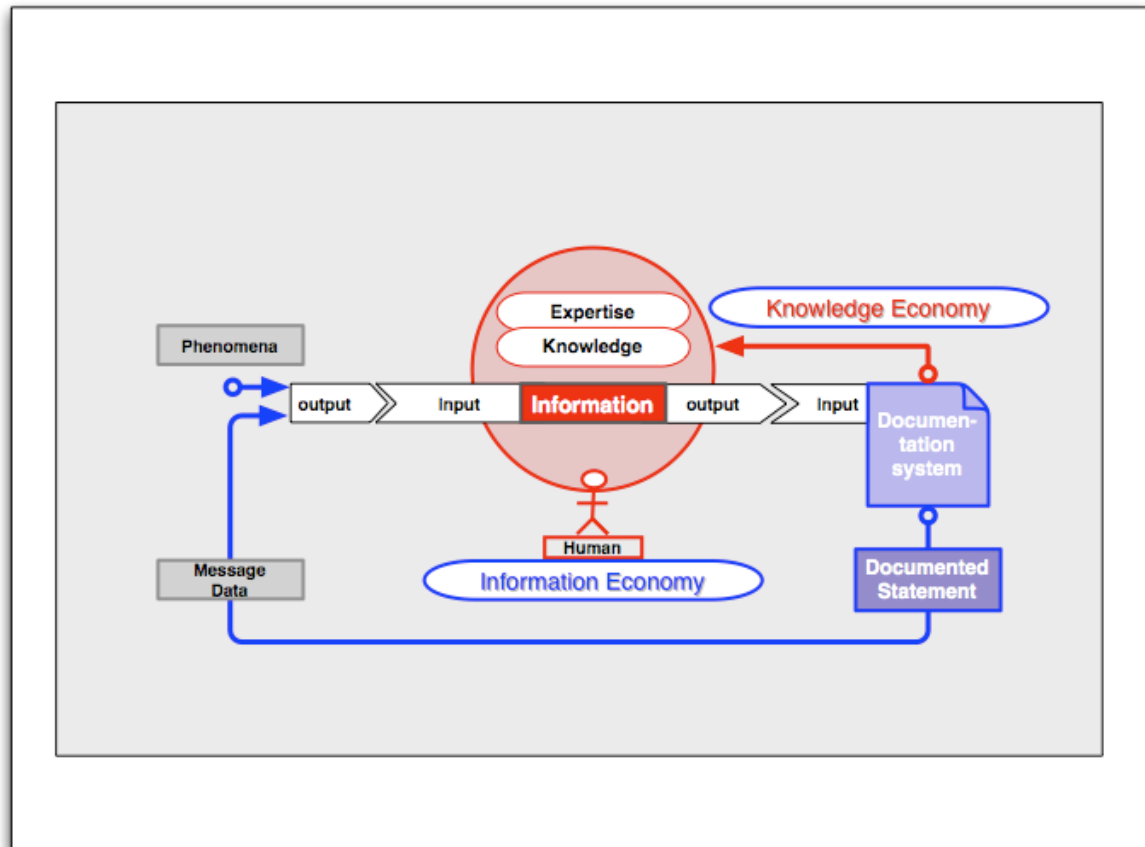http://en.wikipedia.org/wiki/Hermeneutic
http://www.friesian.com/hermenut.htm

Figure 7. Information and knowledge economy

8- Consequences for ICT-industry: migration and transition.

Three European standards are set to make plug-and-play se mantic interoperability between ICT systems possible, by means of an innovative new paradigm. In the future care providers can be optimally supported by mandatory collaboration in networks and chains.

The new standards are going to effect changes in the ICT in-dustry as well. The vertical structure will be replaced with a more horizontally oriented structure (figure 6). Next to value chains there will be ICT value chains. It is clear that the maximum result will be achieved if all health care systems implement the new European (and ISO) standards. To achieve this, the old, non-flexible systems currently in use will have to be replaced entirely. In the literature this is called 'creative destruction'[26]. Systems that have been built on the old paradigm will be unable to deliver the necessary flexibility and quality.

- *New paradigms are -by definition- de-structive technology.*
- *In order to get full plug-and-play se-mantic interoperabil-ity all systems have to be conformant.*
- *This type of migra-tion process is known as creative destruction .*

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[26] http://en.wikipedia.org/wiki/Creative_destruction

9- The natural role of Government.
Quality: requirements, standards, certification

The ambitious common ICT objectives[27] for 2010 that the European member-states have formulated include the one for eHealth in the '*European eHealth Action Plan*'[28]. It can be described briefly as follows:

> '*The action plan sets out a roadmap for greater use of technologies, new services and systems, built around an objective of a 'European e-Health Area'. It identifies practical steps to get there through work on electronic health records... It calls on member-states to develop national and regional e-Health.*'

Within the framework of that e-Health strategy there is a definite role for European R&D and its ensuing European standards.

The implementation of these European EPR related standards implies that systems that are based on the old Messages paradigm will have to be replaced with systems that are based on the new Archetype paradigm. In order to facilitate the essentially necessary transition from the old to the new, specific legislation and regulation will be required. Without this steering the market actors will neither fast nor correctly change and migrate. It is the government's natural role (the Ministry of Health, Welfare and Sport, in the Netherlands) to demand quality from ICT systems in health care. In Europe, in the setting of 'New Approach'[29] European standards are used for the implementation in legislation and regulation and in ICT procurement. As European standards serve as a starting point for reference Implementations[30], the ICT industry can use them for '*compliance testing*'.

Three important developments are underway that help support the governmental processes: OpenEHR, EuroRec and Q-Rec

OpenEHR[31] is an international open source organization that has produced such a Reference Implementation for the EN13606 EHRcom standard.

On a European level, the EuroRec[32] (the European Institute for Health Records) has worked in a 6th Framework project (Q-Rec[33]) on a European system for the testing, evaluation and certification of EHR systems. The role of the Health Care Authorities might in this

- *Europa has ambitious goals for eHealth.*
- *It is the natural role of Governments to pass laws on the quality of infrastructural components.*
- *In Europe this is achieved via the NEW APPROACH.*
- *European standards play an unique role.*
- *Reference Implementation sites are necessary to realise patient safe semantic interoperability between systems.*

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[27] '*i2010 - A European Information Society for growth and employment*' http://europa.eu.int/information_society/eeurope/i2010/index_en.htm

[28] http://europa.eu.int/information_society/activities/health/policy_action_plan/index_en.htm

[29] http://www.newapproach.org

[30] *"In computing, a reference implementation (or, infrequently, sample implementation) is a software example of a standard for use in helping others implement their own versions of the standard. A standard is much easier to understand with a working example to hand."* http://en.wikipedia.org/wiki/Reference_implementation

[31] http://www.OpenEHR.org

[32] http://www.EuroRec.org

[33] Q-Rec is a project by the European Institute for Health Records (EuroRec). 'Quality Labeling and Certification of EHR-systems'

case be limited to controlling the implementation of the standards through a supervision of the certification process.

10- Finally

By developing its standards CEN/TC251 has made a major contribution to supporting collaborating health care professionals and to meeting the obligation to document medical treatment.

Currently work is being undertaken to evaluate these European standards in several national e-Health pilots and to implement them on a large scale in a 7th Frame Work European project. Furthermore, a consortium is in the process of being set up with companies that are the first to create an ICT value chain for supporting health care.

It is clear that the range of implementation of these standards stretches beyond health care. Indeed, the new Archetype paradigm is applicable in any environment that processes documents and records. The wider business community as well as the authorities can no doubt benefit from these recent and interesting developments.

The new Archetype and Template paradigm offers the opportunity to take a huge step forward in the use of electronic records both inside and outside health care.

GF

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• Implementation of standards in legislation and regulation and procurement and public tenders,
• Exchange between ICT systems in healthcare, e-Health and the Electronic Patient Record.

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• Until recently Gerard Freriks worked for TNO, a Dutch contract research organisation,
• Past chairman of CEN/tc251 wg1, he was in charge of producing a number of the standards mentioned,
• Co-author of the Dutch Standard for Information Security in Healthcare,
• Founding member of OIZ (Organisations for ICT in Healthcare in the Netherlands),
• Involved in the European Institute for Health Records (EuroRec),
• Member of Q-Rec project: Quality labeling and Certification of EHR-systems,
• 20 year experience as GP.

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